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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,027	01/05/2006	Koen Van den Heuvel	22409-00009-US	1143

30678 7590 06/16/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
2857	

MAIL DATE	DELIVERY MODE
06/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,027	DEN HEUVEL ET AL.	
	Examiner	Art Unit	
	Jeffrey R. West	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *139,140,144-150,153,155-162,164-171 and 173-180* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *139,140,144-150,153,155-162,164-171 and 173-180* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/19/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 165-171 and 173 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 165-171 and 173 are drawn to a "computer readable medium". The broadest reasonable interpretation of a claim drawn to a computer readable medium covers forms of non-transitory tangible media and transitory propagating signals *per se* in view of the ordinary and customary meaning of computer readable media, particularly when the specification is silent (see MPEP 2111.01). Because the broadest reasonable interpretation covers a signal *per se*, a rejection under 35 USC

101 is appropriate as covering non-statutory subject matter. See 351 OG 212, Feb 23 2010.

The Examiner suggests that Applicant amends the claims as follows: "computer-readable medium" should be ---non-transitory computer-readable medium---.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 139, 140, 144, 147-150, 155, 156, 159-162, 164, 165, 168-171, 173, 174, and 178, as may best be understood, are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,916,291 to Givens et al.

With respect to claim 139, Givens discloses a system for performing after-care of a recipient of a cochlear implant (column 10, lines 49-58 and column 13, lines 47-53) comprising: a clinician subsystem having a clinician interface (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29) configured to receive one or more clinician inputs that at least one of select or customize cochlear implant after-care tests (column 9, lines 35-43, column 15, line 59 to column 16, line 29) and a recipient subsystem (column 8, lines 57-63, column 10, lines 17-24, and column 15,

lines 29-58) configured to receive the one or more selected or customized after-care tests from the clinician subsystem (column 20, lines 15-17 and column 23, lines 41-44 and 54-60) and wherein the recipient subsystem is configured to communicate with the cochlear implant so as to perform the one or more after-care tests selected or customized on the clinician subsystem substantially independent of the clinician subsystem to generate result data indicative of the result of the after-care tests(column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63) for subsequent use by said clinician subsystem (column 13, lines 58-63), wherein the clinician subsystem is further configured to receive the result data from said recipient subsystem (column 9, lines 47-51).

With respect to claim 140, Givens discloses further comprising: a device interface configured to communicatively couple said recipient subsystem and the cochlear implant (column 10, lines 49-58, column 19, lines 34-59 and Figure 11).

With respect to claim 144, Givens discloses wherein said clinician subsystem and said recipient subsystem are physically remote with respect to one another and communicate via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 147, Givens discloses further comprising: a storage medium configured to store said one or more after-care tests (column 14, lines 57-59).

With respect to claim 148, Givens discloses further comprising: a storage medium configured to store said result data (column 9, lines 24-33).

With respect to claim 149, Givens discloses wherein said storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 150, Givens discloses wherein the recipient subsystem is further configured to deliver the result data to the clinician subsystem, and further wherein the clinician subsystem is further configured to perform an assessment of the result data (column 18, lines 63-66).

With respect to claim 155, Givens discloses wherein said clinician subsystem is configured to initiate the one or more after-care tests performed by the recipient subsystem (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 156, Givens discloses a method for performing after-care of a recipient of a cochlear implant comprising (column 10, lines 49-58 and column 13, lines 47-53): receiving one or more inputs at a clinician interface (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29) that at least one of select or customize one or more cochlear implant after-care tests (column 9, lines 35-43 and column 15, line 59 to column 16, line 29), delivering said one or more after-care tests to a recipient subsystem (column 9, lines 35-43), performing, on the cochlear implant, said one or more after-care tests selected or customized on the clinician subsystem to generate result data indicative of the result of the after-care test (column 9, lines 47-51 and column 13, lines 58-63), wherein the after-care tests are performed by the recipient subsystem substantially independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-

44 and 54-63), and delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63).

With respect to claim 159, Givens discloses wherein the recipient subsystem further comprises a storage medium, and wherein the method further comprises storing said one or more after-care tests (column 14, lines 57-59).

With respect to claim 160, Givens discloses further comprising storing said result data in a storage medium of the recipient subsystem (column 9, lines 24-33 and column 23, lines 23-27).

With respect to claim 161, Givens discloses wherein the storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 162, Givens discloses wherein said delivering said one or more after-care tests to the recipient subsystem comprises delivering said one or more after-care tests via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 164, Givens discloses wherein said performing said one or more after-care tests further comprises initializing the one or more tests being performed by the recipient subsystem with inputs received from the clinician interface (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 165, Givens discloses a computer readable medium comprising computer code instructions which, when executed by a computer system (column 8, lines 7-22), implement a method of performing after-care of a recipient of a cochlear implant (column 10, lines 49-58 and column 13, lines 47-53), the method comprising: receiving one or more inputs at a clinician interface that at least one of

select or customize one or more cochlear implant after-care tests (column 8, lines 63-66, column 9, lines 12-24, column 15, line 59 to column 16, line 29), delivering said one or more after-care tests to a recipient subsystem (column 9, lines 35-43), comprising a recipient interface (column 8, lines 57-63, column 10, lines 17-24, and column 15, lines 29-58); performing, on the cochlear implant, said one or more after-care tests selected or customized on the clinician subsystem to generate result data indicative of the result of the after-care tests (column 9, lines 47-51 and column 13, lines 58-63), wherein the after-care tests are performed by the recipient subsystem substantially independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63) and delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63)

With respect to claim 168, Givens discloses wherein the recipient subsystem further comprises a storage medium, and wherein the method further comprises storing said one or more after-care tests in the recipient subsystem (column 14, lines 57-59).

With respect to claim 169, Givens discloses wherein the recipient subsystem further comprises a storage medium, and wherein the method further comprises storing said result data in said recipient subsystem (column 9, lines 24-33 and column 23, lines 23-27).

With respect to claim 170, Givens discloses wherein the storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 171, Givens discloses wherein said delivering said one or more after-care tests to the recipient subsystem comprises delivering said one or more after-care tests via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 173, Givens discloses wherein said performing said one ore more after-care tests further comprises initializing the one or more tests being performed by the recipient subsystem with inputs received from the clinician interface (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 174, Givens discloses a system for performing after-care of a recipient of a cochlear implant (column 10, lines 49-58 and column 13, lines 47-53) comprising: means for receiving one or more inputs via a clinician subsystem (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29) that at least one of select or customize one or more cochlear implant after-care tests (column 9, lines 35-43, column 15, line 59 to column 16, line 29); means for delivering said one or more after-care tests to a recipient subsystem (column 9, lines 35-43); means for performing, on said cochlear implant, said one or more after-care tests on the recipient subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), to generate result data indicative of the result of the after-care tests (column 9, lines 47-51 and column 13, lines 58-63), wherein the after-care tests are performed by the recipient subsystem substantially independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), and means for delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63).

With respect to claim 178, Givens discloses wherein at least one of the one or more after-care tests comprises a comparison of a measured neural response threshold to a previously measured neural response threshold (column 4, lines 3-10 and column 22, lines 11-35).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 145, 146, 153, 157, 158, 166, 167, 175-177, 179, and 180, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Givens in view of U.S. Patent No. 5,626,629 to Faltys et al.

As noted above, the invention of Givens teaches many of the features of the claimed invention, and while the invention of Givens does teach testing, using customized tests, a cochlear implant which generates test results, Givens is not explicit in storing such tests/results in the cochlear implant. Further, while Givens does teach coupling the prosthesis to a recipient subsystem, Givens is not explicit in specifying that the coupling is via a cable. Further still, while Givens teaches performing a plurality of after-care tests, including a comparison of a measured neural response threshold to a previously measured neural response threshold,

Given is not explicit in specifying that at least one of the one or more after-care tests comprises a cochlear implant integrity check, determines whether the dynamic range of each of a plurality of electrodes is set correctly, and/or evaluates the effectiveness of the cochlear implant.

Faltys discloses a system for performing one or more tests (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) on a cochlear implant having one or more implantable components implanted in a recipient (column 5, lines 19-21) comprising: a clinician subsystem, comprising a clinician interface (column 5, lines 35-50), configured to enable a clinician to provide one or more clinician input from said clinician interface to perform one or more of selecting and customizing the one or more tests for the recipient (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); and a recipient subsystem, comprising a recipient interface (column 5, lines 51-66), configured to receive one or more recipient input, from said recipient interface (column 4, lines 22-25), and to generate the result data (column 6, lines 51-55, column 14, line 53 to column 15, line 6), wherein said clinician subsystem is further configured to received said result data from said recipient subsystem (column 8, lines 10-43) wherein the cochlear implant is configured to store said selected or customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61), store said result data (column 9, lines 57-61), and is coupled to said recipient subsystem using a cable (column 5, line 51 to column 6, line 17 and Figure 1). Faltys further teaches wherein at least one of the one or more after-care

tests comprises a cochlear implant integrity check (column 16, lines 19-35), a comparison of a measured neural response threshold to a previously measured neural response threshold (column 7, lines 1-49 and column 8, lines 55-60), determines whether the dynamic range of each of a plurality of electrodes is set correctly (column 4, lines 2-4, column 9, lines 21-49, and column 10, lines 17-25), and/or evaluates the effectiveness of the cochlear implant (column 18, lines 15-22).

It would have been obvious to one having ordinary skill in the art to modify the invention of Givens to explicitly store the tests/results in the cochlear implant, as taught by Faltys, because, as suggested by Faltys, the combination would have improved the system of Givens by storing important information in the cochlear implant itself so that the data will be readily available for future use and/or to provide to a clinician when the network connection fails or during routine in-office clinician visits (column 2, lines 51-65, column 6, lines 51-55 and column 9, lines 40-61).

It would have been obvious to one having ordinary skill in the art to modify the invention of Givens to explicitly specify that the coupling is via a cable, as taught by Faltys, because one having ordinary skill in the art would recognize a cable as a conventional means for connecting a cochlear implant to an interface and, as suggested by Faltys, the combination would have provides a suitable, accurate, and secure means for connecting the prosthesis and interface for communication in Givens (column 5, line 51 to column 6, line 17 and Figure 1).

It would have been obvious to one having ordinary skill in the art to modify the invention of Givens to explicitly specify that at least one of the one or more after-care

tests comprises a cochlear implant integrity check, determines whether the dynamic range of each of a plurality of electrodes is set correctly, and/or evaluates the effectiveness of the cochlear implant, as taught by Faltys, because, as suggested by Faltys, the combination would have improved the overall operation of Givens by ensuring that the cochlear implant is subject to a wider variety of tests for a wider variety of conditions, thereby ensuring that the electrodes are in the correct sequence (column 16, lines 19-35), the electrodes are operating in a proper range (column 4, lines 2-4, column 9, lines 21-49, and column 10, lines 17-25), and that the device provides the best sounding operation (column 18, lines 15-22).

8. Claims 139, 140, 144-150, 153, 155-162, 164-171 and 173-180, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,626,629 to Faltys et al. in view of U.S. Patent No. 5,909,497 to Alexandrescu.

With respect to claim 139, Faltys discloses a system for after-care (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) of a recipient of a cochlear implant (column 5, lines 19-21) comprising: a clinician subsystem having a clinician interface (column 5, lines 35-50), configured to receive one or more clinician inputs that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); and a recipient subsystem (column 5, lines 51-66) configured to receive the one or

more selected or customized after-care tests from the clinician subsystem, and wherein the recipient subsystem is configured to communicate with the cochlear implant to as to perform the one or more after-care tests selected or customized on the clinician subsystem (column 4, lines 22-25) to generate result data indicative of the result of the after-care tests for subsequent use by said clinician subsystem (column 6, lines 51-55, column 14, line 53 to column 15, line 6), wherein the clinician subsystem is further configured to receive the result data from said recipient subsystem (column 8, lines 10-43).

With respect to claim 140, Faltys discloses a device interface configured to communicatively couple said recipient subsystem and the cochlear implant (column 5, line 51 to column 6, line 17 and Figure 1).

With respect to claim 145, Faltys discloses that the cochlear implant is configured to store said one or more after-care tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 146, Faltys discloses that the cochlear implant is configured to store said result data (column 9, lines 57-61).

With respect to claim 147, Faltys inherently discloses a storage medium configured to store said one or more after-care tests (column 6, lines 43-55).

With respect to claim 148, Faltys inherently discloses a storage medium configured to store said result data (column 6, lines 60-63 and column 7, lines 41-65).

With respect to claim 149, Faltys discloses that said storage medium is a portable storage medium (column 22, lines 35-44).

With respect to claim 150, Faltys discloses that the recipient subsystem is further configured to deliver the result data to the clinician subsystem, and further wherein the clinician subsystem is further configured to perform an assessment of the result data (column 8, lines 2-43).

With respect to claim 153, Faltys discloses a cable coupled between said device interface and said cochlear implant (column 5, line 51 to column 6, line 17 and Figure 1)

With respect to claim 155, Faltys discloses that said clinician subsystem is configured to initiate the one or more after-care tests performed by the recipient subsystem (column 15, lines 19-28, column 15, lines 37-48, column 16, lines 36-38).

With respect to claim 156, Faltys discloses a method for performing after-care (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) of a recipient of a cochlear implant (column 5, lines 19-21) comprising: receiving one or more inputs at a clinician interface (column 5, lines 35-50) that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); delivering said one or more after-care tests to a recipient subsystem (column 5, lines 51-66, column 6, lines 51-55 and column 9, lines 40-61), performing, on the cochlear implant, said one or more after-care tests selected or customized on the clinician subsystem to generate result

data indicative of the result of the after-care test (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 157, Faltys discloses further comprising storing said one or more after-care tests in the cochlear implant (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 158, Faltys discloses further comprising storing said result data in the cochlear implant (column 9, lines 57-61).

With respect to claim 159, Faltys inherently discloses that the recipient subsystem further comprises a storage medium and wherein the method further comprises storing said one or more after-care tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 160, Faltys inherently discloses further comprising storing said result data in a storage medium of the recipient subsystem (column 9, lines 57-61).

With respect to claim 161, Faltys discloses that the storage medium is a portable storage medium (i.e. as part of a portable device) (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 164, Faltys discloses that performing said one or more after-care tests further comprises initializing the one or more tests being performed by the recipient subsystem with inputs received from the clinician interface (column 16, lines 36-49).

With respect to claim 165, Faltys discloses a computer readable medium comprising computer code instructions which, when executed by a computer system (column 5, lines 19-25) implement a method of performing after-care of a recipient of a cochlear implant (column 5, lines 19-21), the method comprising: receiving one or more inputs (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) at a clinician interface (column 5, lines 35-50) that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); delivering said one or more after-care tests to a recipient subsystem (column 6, lines 51-55 and column 9, lines 40-61), comprising a recipient interface (column 5, lines 51-66); performing, on the cochlear implant, said one or more after-care tests selected or customized on the clinician subsystem to generate result data indicative of the result of the after-care tests (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 166, Faltys discloses that the method further comprises storing said one or more after-care tests in the cochlear implant (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 167, Faltys discloses that the method further comprises storing said result data in the cochlear implant (column 9, lines 57-61).

With respect to claim 168, Faltys inherently discloses that the recipient subsystem further comprises a storage medium and wherein the method further

comprises storing said one or more after-care tests in the recipient subsystem (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 169, Faltys inherently discloses that the recipient subsystem further comprises a storage medium and wherein the method further comprises storing said result data in said recipient subsystem (column 9, lines 57-61).

With respect to claim 170, Faltys discloses that the storage medium is a portable storage medium (i.e. as part of a portable device) (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 173, Faltys discloses that performing said one or more after-care tests further comprises: initializing the one or more tests being performed by the recipient subsystem with inputs received from the clinician interface (column 16, lines 36-49).

With respect to claim 174, Faltys discloses a system for performing after-care of a recipient of a cochlear implant (column 5, lines 19-21) comprising: means for receiving one or more inputs (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) via a clinician subsystem (column 5, lines 35-50) that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); means for delivering said one or more after-care tests (column 6, lines 51-55 and column 9, lines 40-61) to a recipient subsystem (column 5, lines 51-66); means for performing,

on said cochlear implant, said one or more after-care tests to generate result data indicative of the result of the after-care tests (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and means for delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 175, Faltys discloses that the cochlear implant comprises means for storing said one or more after-care tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 176, Faltys discloses that the cochlear implant comprises means for storing said result data (column 9, lines 57-61).

With respect to claim 177, Faltys discloses wherein at least one of the one or more after-care tests comprises a cochlear implant integrity check (column 16, lines 19-35).

With respect to claim 178, Faltys discloses wherein at least one of the one or more after-care tests comprises a comparison of a measured neural response threshold to a previously measured neural response threshold (column 7, lines 1-49 and column 8, lines 55-60).

With respect to claim 179, Faltys discloses wherein the cochlear implant comprises a plurality of electrodes (column 6, lines 24-26), and wherein at least one of the one or more after-care tests determines whether the dynamic range of each of the plurality of electrodes is set correctly (column 4, lines 2-4, column 9, lines 21-49, and column 10, lines 17-25).

With respect to claim 180, Faltys discloses wherein at least one of the one or more after-care tests evaluates the effectiveness of the cochlear implant (column 18, lines 15-22).

As noted above, the invention of Faltys teaches many of the features of the claimed invention and while the invention of Faltys does teach a computer that process software instructions and output signals to perform testing of a cochlear implant through a recipient interface as well as allowing visualization of results by a clinician through a clinician interface, Faltys does not explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface.

Alexandrescu teaches a programmable hearing aid instrument and programming method thereof including a recipient interface (column 4, lines 4-19) provided by a computer located remote from a clinician interface (column 8, lines 19-33) wherein the recipient interface is operable to obtain software instructions from the hearing prosthesis (column 5, lines 37-49), perform independent testing using the recipient interface (column 8, lines 19-33) and deliver data specific to the hearing prosthesis (i.e. results) electronically to the clinician/specialist interface (column 5, lines 17-20) using the Internet (column 7, line 66 to column 8, line 4).

It would have been obvious to one having ordinary skill in the art to modify the invention of Faltys to explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface, as taught by Alexandrescu, because, as

suggested by Alexandrescu, the combination would have improved the recipient's programming of the device by providing specific programming for the environment in which the recipient is intending to use the device (column 8, lines 19-33) while allowing an experienced specialist to obtain response data from the environment to aid in tailoring the response parameters for the particular environment (column 1, lines 11-18, column 5, lines 17-20, and column 8, lines 5-18).

Response to Arguments

9. Applicant's arguments filed April 19, 2010, have been fully considered but they are not persuasive.

Applicant argues:

> 15. In the outstanding Office Action, the Examiner relies on this "biotelemetry mode" of Givens as evidence that the tests of Givens may be considered "after-care tests." (See, Office Action, pgs. 22-23.) However, as would be apparent from the above, the sections of Givens relied upon by the Examiner (ie. column 4, lines 3-10, and at col. 22, lines 11-35) do not describe any tests whatsoever. Rather, the sections cited by the Examiner only describe one example of how feedback may be obtained from the patient.
>
> 16. Because the "bio-telemetry mode" relied upon the Examiner is merely a method of providing feedback to the audiologist, and does not equate to any type of testing, Applicants submit that Givens fails to disclose "cochlear implant after-care tests."
>
> 17. Furthermore, as noted above, the only test disclosed by Givens is a hearing test in which one or more tones are provided to the patient and patient feedback is gathered to determine whether the patient was able to hear the tone. (See, Givens, col. 9, lns. 35-59.) As would be appreciated such hearing tests are preliminary tests used to determine if a patient is suffering from hearing loss, and which are designed to allow a clinician to determine if the patient is in need of a hearing aid or other hearing prostheses, such as a cochlear implant. Because these hearing tests are so preliminary in nature, the tests would be performed long before a patient would receive a cochlear implant. There would be no reason to assess the hearing loss of a cochlear implant recipient after implantation of the implant because such patients would have already been

> determined to be suffering hearing loss. Therefore, for at least this additional reason, Applicants submit that Givens entirely fails to disclose "cochlear implant after-care tests."
>
> 18. Because Givens fails to disclose "cochlear implant after-care tests," Applicants submit that Givens fails to disclose any type of system that is configured to receive inputs "that at least one of select or customize one or more after-care tests" as recited, in part, in claim 139. Additionally, Applicants submit that Givens fails to disclose any system which is configured to "receive the one or more after-care tests, and.., perform the one or more after-care tests selected or customized on the clinician subsystem." (See, Givens, col. 2, lns. 18- 56.)

After careful consideration of Applicant's arguments and a thorough re-reading of Givens, the Examiner disagrees with Applicant's interpretation of Givens and instead maintains that Givens discloses a clinician interface configured to receive one or more clinician inputs that at least one of select or customize cochlear implant after-care tests (column 9, lines 35-43, column 15, line 59 to column 16, line 29) and a recipient subsystem configured to receive the one or more selected or customized after-care tests from the clinician subsystem (column 20, lines 15-17 and column 23, lines 41-44 and 54-60), specifically:

> As described above, the system can be configured to allow the clinician at the test administration site 10 to control the test sequence and auditory hearing assessment tones from the remote administration site. Thus, the hearing test can be performed such that the hearing tones (frequency and decibel level) are generated and output locally at the patient site 20 in response to commands selecting the desired tone/level which are transmitted from the expert or test administration site to the local site via the computer network. (column 9, lines 35-43)
>
> FIG. 7 illustrates an example of a web page 100 which may be served to the test administration site 10 by the local device 50, 50' to allow control of the local device 50, 50'. As shown, this web page 100 may be provided from the server of the local device 50, 50' to a client, such as a web browser, at the test administration site 10 and includes test control parameters which can be activated and/or adjusted by the clinician during the test. The test parameters shown include a power on control 110, a tone on 120, tone off 130, selectable

frequency, and independently selectable left and right intensity controls 146, 147. The power on control 110 can activate the tone generator 55 or function generator 56 at the local site 20 (deselecting this control then powers off or deactivates the tone generator 55). The tone on and tone off controls 120, 130 are typically operably associated with an attenuator and/or output switch and allows the clinician to control the length (or to initiate at desired intervals and terminate the sound when the response is indicated) of the tone signal output to the patient at the local site. The select frequency control 145 allows the clinician to adjust the test frequency and order of the testing protocol. The left and right intensity controls 146, 147 allow the clinician to adjust the intensity in the desired ear for each frequency selected. The data box 150 identifies the sound pressure level correction for each frequency. The exemplary screen display shown is for discussion purposes and, it is noted that, the screen layout, test parameters, and activation and/or control features may vary. (column 15, line 59 to column 16, line 29)

Thus, the local device can be configured to allow a local operator to power up and depress a "ready button" when the probe assembly is in position. (column 20, lines 15-17)

The client 1600 displays the status information for the operator and determines, for example, by receiving input from the operator, if any parameters are to be changed (block 1720). When no parameters are to be changed (block 1720), the client 1600 instructs the web server 1610 to initiate the stimulation (block 1735). The web server 1610 initiates the stimulation by the audiometer 1620, either directly or through the interface 1615, and collects data on the patient response (block 1740), either directly or through the interface 1615. (column 23, lines 41-44 and 54-60)

While Applicant argues that “the ‘bio-telemetry mode’ relied upon the Examiner is merely a method of providing feedback to the audiologist, and does not equate to any type of testing”, the Examiner asserts that column 15, line 59 to column 16, line 29 clearly describes a test.

Additionally, since the tests being performed is on a cochlear implant recipient, the Examiner asserts that one having ordinary skill in the art would consider the tests to be "after-care" since the implant has already been received.

Applicant argues:

> 19. Applicants claim 139 further recites that the "recipient subsystem is configured to communicate with the cochlear implant so as to perform the one or more after-care tests... substantially independent of the clinician subsystem." (See, claim 139, above.) As detailed above, the system of Givens performs hearing tests to assess a patient's hearing loss. (See, Givens, col. 8, ln. 63- col. 9, ln. 15.) Specifically, the testing systems of Givens delivers audible tones to the patient, and does not operate with any hearing device, let alone a cochlear implant.

The Examiner disagrees with Applicant's interpretation of Givens and instead maintains that Givens discloses that the recipient subsystem is configured to communicate with the cochlear implant so as to perform the one or more after-care tests selected or customized on the clinician subsystem substantially independent of the clinician subsystem to generate result data indicative of the result of the after-care tests (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), specifically:

> The local device 450, as for devices 50, 50', can be configured as a stand alone device (as shown), preferably with signal and data processing capability, and remote communication link 450c (whether via one or more of wireless, tower or satellite transmission, cable, telephone, fiber optic, or other communication link) so as to be able to transfer or upload data to (and preferably from as well) the remote location. In certain embodiments, the local device 450 is portable and may be implemented as a pervasive computing device that is configured to generate the desired test signals and to receive the response signals and relay the information to the remote site via the communication link 450c. (column 19, lines 48-60)

Referring to FIG. 11, in operation, in certain embodiments, the local device 450 is configured to generate stimulation signals corresponding to the testing protocol associated with the desired test (such as middle ear compliance or distortion product type evaluations). The stimulation signals 480 are transmitted from an output source located in the ear probe assembly 475, such as one or more speakers 482 having suitable operating characteristics in the desired frequency range (such as model ER-2 speakers from Etymotic Research Corporation, believed to have a relatively flat response from about 200 Hz-10 kHz). The probe assembly 475 can also include one or more sensors 483 such as transducers and/or one or more miniaturized low noise microphones oriented and configured to sense signals evoked in the ear of the subject. The sensor 483 detects the evoked response signal and relays the signal (typically as a digital signal converted by an A/D converter, as well known to those of skill in the art) to the local device 450. The local device 450 can directly relay the detected signals in the form in which they are received. Alternatively, the local device 450 (or associated computer or signal processor) can process the received signals into a desired format before transmitting to the remote site. (column 20, lines 24-46)

FIG. 17 illustrates operations according to embodiments of the present invention. The operations illustrated in FIG. 17 may be carried out by the system of FIG. 16. As seen in FIG. 17, the client 1600 pings the web server 1610 (block 1700). If a response to the ping is not received (block 1705), operations may terminate or the ping of a same IP address or a different IP address may be performed until a response is received. If a response to the ping is received (block 1705), the client 1600 initiates a status request to the web server 1610 (block 1710). The web server 1610 collects the requested status information, for example, by requesting information from the audiometer 1620, and returns the status information to the client 1600 (block 1715). The client 1600 displays the status information for the operator and determines, for example, by receiving input from the operator, if any parameters are to be changed (block 1720).

When no parameters are to be changed (block 1720), the client 1600 instructs the web server 1610 to initiate the stimulation (block 1735). The web server 1610 initiates the stimulation by the audiometer 1620, either directly or through the interface 1615, and collects data on the patient response (block 1740), either directly or through the interface 1615. The response data is provided to the client 1600 (block 1745) for display to the operator. If more tests are to be performed (block 1750), operations may continue from block 1720. (column 23, lines 29-44 and 54-63)

While Applicant argues, “the testing systems of Givens delivers audible tones to the patient, and does not operate with any hearing device”, the Examiner asserts that the testing is clearly performed by communicating with an in-ear assembly, as can be seen by the cited sections above, and such an in-ear assembly is illustrated below in Figure 11:

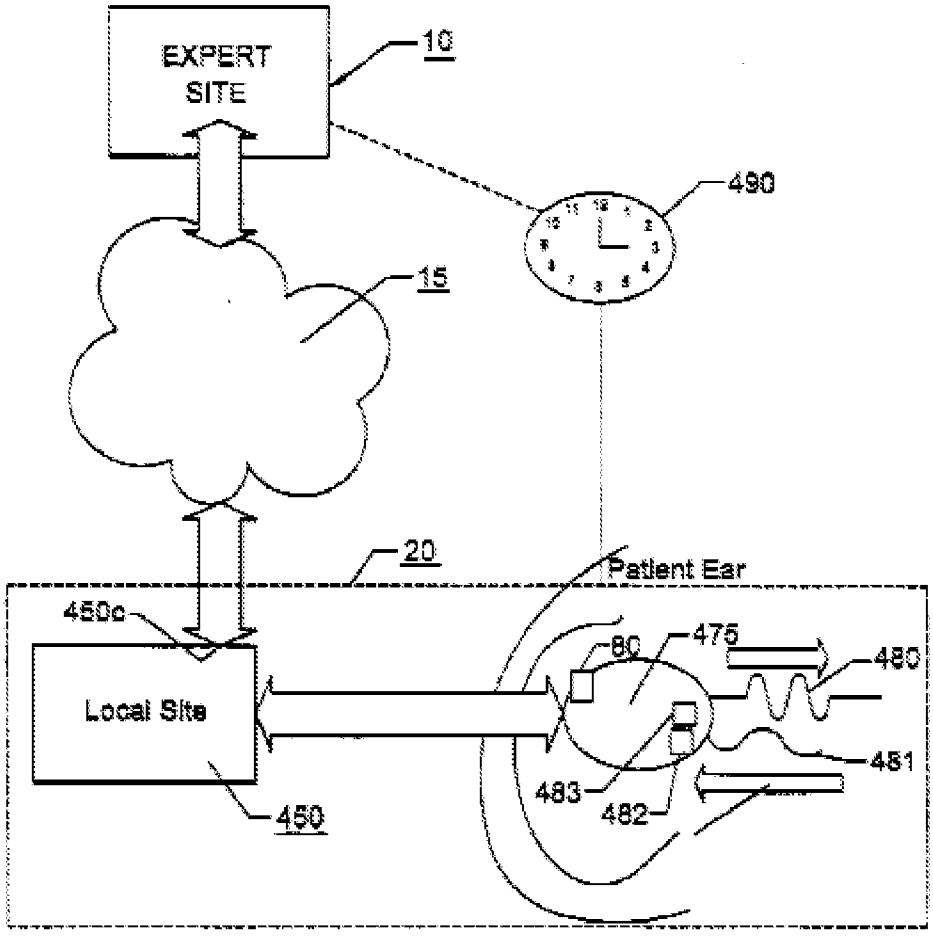

FIG. 11.

Applicant argues:

> 21. Applicants claim 139 further recites that the "recipient subsystem is configured to perform the one or more after-care tests.., **substantially independent** of the clinician subsystem." (See, claim 139, above; emphasis added.) It is clear from Givens that the tests discloses therein cannot be performed "substantially independent of the clinician subsystem." Specifically, as explained above, the hearing diagnostic tests of Givens are controlled by the clinician through the patient's remote terminal. (See, Givens, col. 8, ln. 63- col. 9, ln. 15.) The clinician uses different types of feedback from the patient to proceed through the test. (See, Givens, col. 8, ln. 63- col. 9, ln. 15.) For example, in certain circumstances, verbal feedback from the patient indicates that a delivered tone is or is not audible, and the clinician uses this indication to adjust the next tone to be delivered. (See, Givens, col. 8, ln. 63- col. 9, ln. 15.) Therefore, because of this large amount of control required of the clinician, the alleged "recipient subsystem" of Givens is not configured to "perform the one or more after-care tests selected or customized on the clinician subsystem substantially independent of the clinician subsystem" as recited, in part, in claim 139. (Emphasis added.)

The Examiner disagrees with Applicant's interpretation of Givens and instead the Examiner maintains that since the local device 450 "can be configured as a stand alone device" and "is configured to generate stimulation signals", Givens discloses that the recipient subsystem is configured to communicate with the cochlear implant so as to perform the one or more after-care tests selected or customized on the clinician subsystem substantially independent of the clinician subsystem to generate result data indicative of the result of the after-care tests (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), specifically:

The local device 450, as for devices 50, 50', can be configured as a stand alone device (as shown), preferably with signal and data processing capability, and remote communication link 450c (whether via one or more of wireless, tower or satellite transmission, cable, telephone, fiber optic, or other communication link) so as to be able to transfer or upload data to (and preferably from as well) the remote location. In certain embodiments, the local device 450 is portable and may be implemented as a pervasive computing device that is configured to generate the desired test signals and to receive the response signals and relay the information to the remote site via the communication link 450c. (column 19, lines 48-60)

Referring to FIG. 11, in operation, in certain embodiments, the local device 450 is configured to generate stimulation signals corresponding to the testing protocol associated with the desired test (such as middle ear compliance or distortion product type evaluations). The stimulation signals 480 are transmitted from an output source located in the ear probe assembly 475, such as one or more speakers 482 having suitable operating characteristics in the desired frequency range (such as model ER-2 speakers from Etymotic Research Corporation, believed to have a relatively flat response from about 200 Hz-10 kHz). The probe assembly 475 can also include one or more sensors 483 such as transducers and/or one or more miniaturized low noise microphones oriented and configured to sense signals evoked in the ear of the subject. The sensor 483 detects the evoked response signal and relays the signal (typically as a digital signal converted by an A/D converter, as well known to those of skill in the art) to the local device 450. The local device 450 can directly relay the detected signals in the form in which they are received. Alternatively, the local device 450 (or associated computer or signal processor) can process the received signals into a desired format before transmitting to the remote site. (column 20, lines 24-46)

FIG. 17 illustrates operations according to embodiments of the present invention. The operations illustrated in FIG. 17 may be carried out by the system of FIG. 16. As seen in FIG. 17, the client 1600 pings the web server 1610 (block 1700). If a response to the ping is not received (block 1705), operations may terminate or the ping of a same IP address or a different IP address may be performed until a response is received. If a response to the ping is received (block 1705), the client 1600 initiates a status request to the web server 1610 (block 1710). The web server 1610 collects the requested status information, for example, by requesting information from the audiometer 1620, and returns the status information to the client 1600 (block 1715). The client 1600 displays the status information for the operator and determines, for example, by receiving input from the operator, if any parameters are to be changed (block 1720).

When no parameters are to be changed (block 1720), the client 1600 instructs the web server 1610 to initiate the stimulation (block 1735). The web

server 1610 initiates the stimulation by the audiometer 1620, either directly or through the interface 1615, and collects data on the patient response (block 1740), either directly or through the interface 1615. The response data is provided to the client 1600 (block 1745) for display to the operator. If more tests are to be performed (block 1750), operations may continue from block 1720. (column 23, lines 29-44 and 54-63)

Applicant argues:

29. Faltys is directed to a system for fitting or programming a cochlear stimulation system for a patient utilizing objective measurements rather than subjective feedback. (See, Faltys, col. 3, lns. 29-47.) In Faltys, the clinician utilizes the fitting system to instruct the cochlear implant system to deliver an electrical stimulation signal to the patient. (See, Faltys, col. 5, ln. 52-col. 6, ln. 42.) The fitting system records an objective measurement of the patient's response to the stimulation. (See, Faltys, col. 6, lns. 32- col. 8, ln. 23.) Based on the objective measurement, the clinician adjusts the stimulation provided. (See, Faltys, col. 6, lns. 32- col. 8, ln. 23.) This procedure is iteratively repeated to determine a patient's threshold and comfort levels. (See, Faltys, col. 6, lns. 32- col. 8, ln. 23.) In other words, the system of Faltys requires a clinician to operate the tests, evaluate objective feedback and adjust stimulation signals applied to the patient. (See, Faltys, col. 6, lns. 32- col. 8, ln. 23.) Due to this large amount of clinician involvement required, Applicants submit that it is impossible for any element of the system to perform any tests "substantially independent of the clinician subsystem" as recited, in part, in claim 139. (Emphasis added.)

The Examiner asserts that the invention of Faltys is not relied upon to teach independent testing as the Office Action specifically states that “while the invention of Faltys does teach a computer that process software instructions and output signals to perform testing of a cochlear implant through a recipient interface as well as allowing visualization of results by a clinician through a clinician interface, Faltys does not explicitly indicate that the interfaces are provided by separate remote

computers connected by the Internet to allow independent testing to be performed by the recipient interface."

Instead the Examiner asserts that such a feature is taught by Alexandrescu which specifically teaches a programmable hearing aid instrument and programming method thereof including a recipient interface (column 4, lines 4-19) provided by a computer located remote from a clinician interface (column 8, lines 19-33) wherein the recipient interface is operable to obtain software instructions from the hearing prosthesis (column 5, lines 37-49), perform independent testing using the recipient interface (column 8, lines 19-33) and deliver data specific to the hearing prosthesis (i.e. results) electronically to the clinician/specialist interface (column 5, lines 17-20) using the Internet (column 7, line 66 to column 8, line 4).

Further, the Examiner maintains that it would have been obvious to one having ordinary skill in the art to modify the invention of Faltys to explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface, as taught by Alexandrescu, because, as suggested by Alexandrescu, the combination would have improved the recipient's programming of the device by providing specific programming for the environment in which the recipient is intending to use the device (column 8, lines 19-33) while allowing an experienced specialist to obtain response data from the environment to aid in tailoring the response parameters for the particular environment (column 1, lines 11-18, column 5, lines 17-20, and column 8, lines 5-18).

Applicant argues:

> 37. Applicants submit that Alexandrescu completely fails to disclose any type of testing, let alone "cochlear implant after-care" testing. Rather, Alexandrescu merely discloses that the hearing aid is capable of receiving and implementing programming codes. Applicants assert that a hearing aid configured to received "programming" is not the same as testing and, as such, Alexandrescu cannot disclose a recipient subsystem configured to "perform the one or more after-care tests selected or customized on the clinician subsystem substantially independent of the clinician subsystem" as recited, in part, in claim 139.
>
> 38. Furthermore, Alexandrescu is exclusively directed to a system for providing programs to an acoustic hearing aid. (See, Alexandrescu, col. 3, ln. 59-col. 4, ln. 19.) Not only is the testing of Alexandrescu not equivalent to "after-care of a recipient of a cochlear implant," but the system of Alexandrescu also completely fails to disclose any type of system that is configured to receive inputs "that at least one of select or customize one or more after-care tests" as recited, in part, in claim 139.

The Examiner asserts that, as noted above, the invention of Alexandrescu is only relied upon to modify the invention of Faltys to explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface.

The Examiner further maintains that selection or customization of one or more after-care tests is disclosed by Faltys with Faltys disclosing a system for after-care (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) of a recipient of a cochlear implant (column 5, lines 19-21) comprising: a clinician subsystem having a clinician interface (column 5, lines 35-50), configured to receive one or more clinician inputs that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and

column 22, lines 51-53); and a recipient subsystem (column 5, lines 51-66) configured to receive the one or more selected or customized after-care tests from the clinician subsystem, and wherein the recipient subsystem is configured to communicate with the cochlear implant to as to perform the one or more after-care tests selected or customized on the clinician subsystem (column 4, lines 22-25) to generate result data indicative of the result of the after-care tests for subsequent use by said clinician subsystem (column 6, lines 51-55, column 14, line 53 to column 15, line 6), wherein the clinician subsystem is further configured to receive the result data from said recipient subsystem (column 8, lines 10-43).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 6,334,072 to Leysieffer teaches a system for performing a test on a hearing prosthesis implanted in a recipient (column 8, lines 24-26) comprising: a testing computer (column 6, lines 49-52) comprising a processor configured to process software instructions and to output signals in response to said processed software instructions (column 7, lines 38-52); a prosthesis interface configured to transfer said outputted signals from said testing computer to the hearing prosthesis interfaced with said testing computer (column 6, lines 45-64); and a recipient interface configured to receive a control input from the recipient of the hearing and to

cause said processor to perform said test in response to said control input (column 6, line 65 to column 7, line 7).

U.S. Patent No. 6,115,478 to Schneider teaches an apparatus for and method of programming a digital hearing prosthesis comprising a local system and computer and a remote system and computer wherein the remote system controls the local system to initiate synthesizing signals for transmission to the hearing prosthesis (column 9, lines 50-58).

U.S. Patent No. 6,879,693 to Miller et al. teaches a method and system for external assessment of hearing aids that include implanted actuators.

U.S. Patent Application Publication No. 2002/0176584 to Kates teaches an apparatus and methods for hearing aid performance measurement, fitting, and initialization.

U.S. Patent No. 6,366,863 to Bye et al. teaches a portable hearing-related analysis system.

U.S. Patent No. 6,115,478 to Schneider teaches an apparatus and method of programming a digital hearing aid.

U.S. Patent No. 4,847,617 to Silvian teaches a high speed digital telemetry system for implantable devices.

U.S. Patent No. 5,609,616 to Schulman et al. teaches a physician's testing system and method for testing an implantable cochlear stimulator.

U.S. Patent No. 7,181,297 to Pluvinage et al. teaches a system and method for delivering customized audio data.

EP Patent Application Publication No. 0 124 930 to Crosby et al. teaches a cochlear implant system for an auditory prosthesis.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY R. WEST whose telephone number is (571)272-2226. The examiner can normally be reached on Monday through Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eliseo Ramos-Feliciano can be reached on (571)272-7925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey R. West/
Primary Examiner, Art Unit 2857

June 16, 2010